

Serial No.: 10/505,289  
Docket No.: 01898-25808.US

### REMARKS

Applicants express appreciation to the Examiner for consideration of the subject patent application. In this application, claims 1-17 are currently under consideration, while claims 18-33 have been withdrawn. This communication is in response to the Office Action mailed July 2, 2008, in which the following actions were taken:

(1) Claims 1-17 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement;

(2) Claims 1-17 were rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,103,112 to Sutton et al. (hereinafter "Sutton"); and

(3) Claims 5, 6, 9, and 15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sutton in view of U.S. Patent No. 6,423,120 to Nickerson et al. (hereinafter "Nickerson");

(4) Claims 1-17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sutton in view of each of U.S. Patent No. 5,238,557 to Schneider et al. (hereinafter "Schneider"), Applicants' specification, and U.S. Patent No. 3,522,725 to Waters (hereinafter "Waters"); and

(5) Claims 5, 6, 9, and 15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sutton in view of each of Schneider, Applicants' specification, and Waters and further in view of Nickerson.

Reconsideration of the application is respectfully requested in view of the present amendment and following responsive remarks. For the Examiner's convenience and reference, Applicants' remarks are presented in the order in which the corresponding issues were raised in the Office Action.

#### Claim Rejections - 35 U.S.C. § 112

Claims 1-17 stand rejected under § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner has stated that the language "wherein said heating or cooling is



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performed away from the column" and "situated separately from the column" lack support. The Examiner has stated further that the specification does not support precluding direct thermal contact between the heating or cooling source. In making this assertion, the Examiner points to Figure 1 as representing an embodiment of the invention. Applicants submit that the claims discussed were not directed to and did not support that particular embodiment, and further that this even more true for the present claims. Rather, as stated above and in Applicants' amendment sent June 10, 2008, Figure 2 (not Figure 1) sets forth an embodiment encompassed by the claims and is compatible with the claimed method. As can be seen in Figure 2, preheating apparatus 10 is separately situated from column 16 and has no contact therewith. In addition, Applicants' specification also supports this limitation in describing distance between the heating element and the column. Pg. 5, lines 4-8. In such an arrangement, there will be no contact between element and the column, in accordance with the present claims. Therefore, Applicants submit that the present claims are fully supported by the specification as originally filed, and that neither the previous nor the present amendment introduce new matter.

#### **Claim Rejections - 35 U.S.C. § 102**

The Examiner has rejected claims 1-17 under 35 U.S.C. § 102(b) as anticipated by Sutton. Sutton discloses a chromatographic apparatus in which heating or cooling is provided by either moving air from a fan or a conduction source in metal-to-metal contact with a heat conducting block in which the chromatography column and inlet tubing are embedded. See e.g. Figures 4-7 and 9. In one embodiment in Sutton, the inlet tubing is coiled in a receptacle in the heat conducting block. In another embodiment disclosed in Sutton, the inlet tubing is enclosed in a labyrinth within the block. In all of these embodiments, the column is in direct thermal contact with the source of heating or cooling, so that at least some heating or cooling of the fluid occurs in the column. The presently claimed method requires use of a heating or cooling member having no contact with the column. The apparatus disclosed by Sutton is clearly not compatible with the methods of the present claims, in that the separation column of each Sutton apparatus is located within the temperature modification means.

Applicants also reiterate that, contrary to the Examiner's assertions, Sutton fails to teach the use of a temperature sensor in accordance with claim 10. This claim requires a temperature



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sensor connected to a portion of the tube closer to the separation column than the portion to which the heating/cooling member is connected. In asserting that Sutton teaches this limitation, the Examiner has referred to an embodiment shown in Figure 7 of Sutton and stated that "temperature sensor 118 is closer to that portion of tubing 114 closer to column 106 than emerging from prefilter 98." Applicants submit that the Examiner's observation only further reveals the shortcomings of Sutton. The portion of tubing 114 to which the Examiner refers is itself the portion to which the heating/cooling member is connected. Therefore, by being closer to said portion, it is by definition not closer to the column and therefore does not read on claim 10. Furthermore, Applicants reiterate that the temperature sensor 118 is not connected to any portion of the tubing and therefore also fails to meet the requirements of claim 10.

As Sutton fails to teach each and every element of the present independent claims 1, 9, and 10, that reference does not anticipate those claims. The same is true of claims 2-8 and 11-17, which each include the limitations of claims 1 or 10. Therefore, Applicants respectfully request that this rejection be withdrawn.

#### **Claim Rejections - 35 U.S.C. § 103**

Claims 1-17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sutton alone or Sutton in view of Nickerson. Applicants submit that the present claims 1-17 are patentable over these references. Each rejection will be discussed below in turn.

#### **Rejection over Sutton alone**

In the alternative to the above rejection under § 102, the Examiner has also rejected claims 1-17 under 35 U.S.C. § 103(a) as being unpatentable over Sutton. The failure of Sutton to teach each and every element of the present claims is discussed above and Applicants hereby reassert these arguments here. In summary, the apparatus of Sutton cannot be employed in the methods claimed by Applicants. In particular, those apparatus place the separation column within the means of heating or cooling and in direct thermal contact with said means. There is no suggestion in Sutton of heating or cooling in a separate part of the apparatus not in contact with the column. Rather, by their structure and design (i.e. a block or enclosure containing



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substantially the entire chromatography apparatus) the apparatus in Sutton do not admit of such an approach as set forth in the present claims. Any modification to these apparatus that would make them compatible with the methods of the present claims would require drastic changes that would constitute more than routine optimization. Therefore, Applicants submit that Sutton does not support a *prima facie* case of obviousness of the pending claims, and request the withdrawal of this rejection.

Rejection over Sutton in view of Nickerson

The Examiner has rejected claims 5, 6, 9, 15 under 35 U.S.C. § 103(a) as being unpatentable over Sutton in view of Nickerson. Specifically, Nickerson is cited to provide a teaching of the rates of temperature modification required by Applicants' claims. The shortcomings of Sutton with regard to the present claims are discussed above and also apply here. Nickerson does not remedy these shortcomings, in that Nickerson does not teach or suggest a method using a heating/cooling member situated separately from the separation column and having no contact with the separation column. On the contrary, Nickerson discloses an arrangement in which the column is inside or closely associated with the heater. See Figure 2.

Applicants reiterate the assertion that the heating rate recited in the rejected claims is not obvious over Nickerson. More specifically, the combination of references does not teach or suggest any particular heating rate as applied to the heated medium. While Nickerson does discuss the power configuration of heaters, there is no teaching in Nickerson of the actual heating/cooling rates undergone by the mobile phase itself. As such, Applicants submit that the language "reasonable heat-up rates" as used in Nickerson is insufficient to constitute a teaching or suggestion of a given mobile phase heating rate.

In view of the above, Applicants submit that Nickerson does not support a *prima facie* case of obviousness in combination with Sutton, because these references do not teach or suggest every element of the present claims. Withdrawal of this rejection is respectfully requested.

Rejections over Sutton in view of Schneider, specification, or Waters

The Examiner has rejected claims 1-17 under 35 U.S.C. § 103(a) as being unpatentable over Sutton in view of each Schneider, Applicants' specification, and Waters. The Examiner



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has also rejected claims 5, 6, 9, and 15 over these combinations and further in view of Nickerson. The shortcomings of Sutton and Nickerson with regard to these claims are discussed above and are incorporated in the discussion of these rejections. Applicants now turn to the other disclosures asserted to support these rejections.

The Examiner has cited Schneider and Waters as teaching heating/cooling away from the column, as required by previously presented claims. While not conceding that either reference provides such a teaching that would render the previously presented claims obvious, Applicants submit that the rejection is moot in view of the current amendment. Schneider teaches preheating by using heated mobile phase from the column which is itself in thermal contact with a heating member through a receiving piece 7. See Fig. 1. The paragraph of Applicants' specification bridging pages 2 and 3 only discusses control of preheating means without mentioning any particular situation of such a means, whether it be one in the prior art or that claimed by Applicants. Waters discloses a heating system comprising a heating block in which the separation apparatus is enclosed. The column is made of thermally-conductive material and is in direct thermal contact with the heating block at both ends via thermally-conductive tubes. Col. 3, lines 33-37 and Figure. As such, none of the disclosures teach or suggest a method using a heating/cooling means having no contact with the separation column.

In view of the above, Applicants submit that present claims 1-17 are patentable over the combination of disclosures asserted by the Examiner, because this combination fails to teach or suggest every element of the present claims. Withdrawal of these rejections is respectfully requested.



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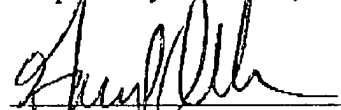
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In light of the above, Applicants respectfully submit that pending claims 1-17 are now in condition for allowance. Therefore, Applicants request that the rejections and objections be withdrawn, and that the claims be allowed and passed to issue. If any impediment to the allowance of these claims remains after entry of this Amendment, the Examiner is strongly encouraged to call Gary P. Oakeson at (801) 566-6633 so that such matters may be resolved as expeditiously as possible.

The Commissioner is hereby authorized to charge any additional fee or to credit any overpayment in connection with this Amendment to Deposit Account No. 20-0100.

DATED this 18<sup>th</sup> day of August, 2008.

Respectfully submitted,



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